

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

MARGARET HALTON PRIEST,	§	
individually and as Representative of the	§	
Estate of NOEL LAJOIE PRIEST,	§	
Plaintiff,	§	
V.	§	A-15-CV-00822-LY-ML
	§	
SANDOZ, INC.,	§	
Defendant.	§	

**ORDER AND REPORT AND RECOMMENDATION
OF THE UNITED STATES MAGISTRATE JUDGE**

TO THE HONORABLE LEE YEAKEL
UNITED STATES DISTRICT JUDGE:

Before the court are Defendant Sandoz, Inc.’s (“Sandoz”) Motion to Exclude Testimony of Pamela Kulback, M.D. In Part (Dkt. #86); Sandoz’s Motion to Exclude the Testimony of Richard Friedlander, M.D., In Part (Dkt. #88); Sandoz’s Motion to Exclude the Testimony of Daniel Buffington, Pharm.D., In Part (Dkt. #88); Sandoz’s Motion for Summary Judgment (Dkt. #92); and all related briefing.¹ After reviewing the pleadings, the relevant case law, as well as the entire case file, the undersigned issues the following Order and Report and Recommendation to the District Court.

I. BACKGROUND

Plaintiff² alleges Noel Priest died from taking amiodarone, a generic version of a prescription medication, Cordarone.³ According to the First Amended Complaint (“FAC”),⁴ Mr.

¹ Pursuant to 28 U.S.C. § 636(b), Rule 72 of the Federal Rules of Civil Procedure, and Rule 1 of Appendix C of the Local Rules of the United States District Court for the Western District of Texas, United States District Judge Lee Yeakel referred all dispositive motions to the undersigned for a Report and Recommendation as to the merits and all nondispositive motions for resolution.

² Margaret Priest brings this suit individually and as representative of her late husband, Noel Priest’s, estate. For clarity, the undersigned refers to Noel Priest as Mr. Priest; Margaret Priest the individual as Mrs. Priest; and Margaret Priest as Plaintiff, where she is acting in that capacity.

Priest was prescribed amiodarone as a treatment for an irregular heartbeat, an “off-label” use of the drug. Dkt. #25 (FAC) at ¶ 78. Mr. Priest filled his prescription at a Kroger Pharmacy and took the medication as prescribed. *Id.* at ¶ 79. Mr. Priest allegedly did not receive a Medication Guide,⁵ which outlines the risks and benefits of the drug, with his prescription. *Id.* at ¶ 81. He was not informed of the potentially fatal side effects associated with the drug. *Id.* at ¶¶ 81-82. Mr. Priest was not aware that his use of the drug was an “off-label” use. *Id.* at ¶¶ 79, 84. Mr. Priest died on March 17, 2014, allegedly from complications associated with his use of amiodarone. *Id.* at ¶ 91. Plaintiff alleges that “[h]ad [Mr. Priest] been provided the Medication Guide, he would have been aware of the serious lung related side effects that could lead to death as well as other issues and he would not have taken Amiodarone.” *Id.* at ¶ 81.

It is undisputed that in early 2014, Mr. Priest aspirated some of his stomach contents, which led to an infection, sepsis, multi-organ failure, and his eventual death. Dkt. #92 at 2; Dkt. #110 at ¶¶ 23-28. However, the parties dispute what caused him to aspirate. Plaintiff contends the aspiration was caused by complications from amiodarone induced pulmonary toxicity (“AIPT”). Sandoz disputes whether Mr. Priest suffered from AIPT and whether it caused the aspiration.

The parties also dispute whether Mr. Priest received a “Medication Guide” when he filled his amiodarone prescriptions, which describes the risks of amiodarone. As the drug manufacturer, Sandoz was required to ensure that FDA-approved Medication Guides were available for distribution to patients by either providing amiodarone distributors or authorized

³ The undersigned’s previous Report and Recommendation described the regulatory scheme governing branded and generic prescription drugs as well as issues of federal preemption for state law claims. Dkt. #65 (“First R&R”).

⁴ These are the facts as stated in the FAC.

⁵ “The FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects; patient decision-making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product are essential to its effectiveness. <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>.” FAC at ¶ 81 n.19.

dispensers with sufficient numbers of Medication Guides or with the means to produce the Medications Guides. 21 C.F.R. § 208.24(a),(b).

Plaintiff brought this action against Sandoz, asserting four causes of action, A-D, in the FAC. Plaintiff's first cause of action (Count A) was for Wrongful Death, asserting "[t]he death of Noel Lajoie Priest was directly and proximately cause by the negligent actions of the Defendant as related to the manufacture, marketing, distribution and sale of Amiodarone as described herein." *Id.* at ¶ 119. Plaintiff's second cause of action (Count B) was for Gross Negligence. Plaintiff alleged Sandoz was grossly negligent in failing to provide the FDA-required Medication Guide. *Id.* at ¶¶ 123-126. Plaintiff's third cause of action (Count C) alleged Sandoz's marketing and promotion of amiodarone for off-label uses proximately caused Noel Priest's death. *Id.* at ¶¶ 128-31. Plaintiff's fourth cause of action (Count D) was that "Sandoz's failure to provide the Medication Guide renders Sandoz's sales of amidrone [sic] illegal, and Sandoz's sales therefore constituted negligence per se." *Id.* at ¶ 133.

Sandoz moved to dismiss the FAC on several grounds, in part relying on a previous Report and Recommendation in a nearly identical case, *Rusk v. Sandoz Inc.*, No. A-14-CV-549-LY, Dkt. #34 ("First *Rusk* Report and Recommendation"), which gave Plaintiff specific instructions for meeting the pleading standards for the off-label marketing and failure to provide a Medication Guide claims. Sandoz argued that any claims related to manufacture, marketing, distribution, and sale of amiodarone were preempted as a matter of law, as held in the First *Rusk* Report and Recommendation, and Plaintiff failed to adequately plead her claims as taught by the First *Rusk* Report and Recommendation. Dkt. #28.

The undersigned recommended that the wrongful death claim (Count A) be dismissed as preempted, Dkt. #65 (First R&R) at 10-11; that "[t]o the extent Plaintiff seeks to allege that

Sandoz failed to comply with its obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused Mr. Priest to take amiodarone without knowledge of the FDA-approved warnings, such a claim [Counts B and D] would survive federal preemption” and was adequately pleaded, *id.* at 11-12, 15-17 (citing *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014)); and Plaintiff’s off-label marketing and promotion claim (Count C) should be dismissed because Plaintiff failed to plead sufficient facts that plausibly stated a claim for relief, *id.* at 21-25. The District Court accepted and adopted the undersigned’s Report and Recommendation and dismissed Plaintiff’s wrongful death and off-label marketing claims with prejudice. Dkt. #67.

Now before the court are Sandoz’s *Daubert* and summary judgment motions. Sandoz moves for summary judgment on the bases that it provided Medication Guides to Kroger, that Plaintiff cannot meet her burden of proof to show Priest’s death was caused by amiodarone, and that Plaintiff does not have clear and convincing proof of gross negligence. Sandoz moves to exclude the testimony of Richard Friedlander, M.D., and Pamela Kulback, M.D., who opine on the cause of Priest’s death and medical issues. Sandoz also moves to exclude the testimony of Daniel Buffington, Pharm.D., who opines that Sandoz’s provision of Medication Guides did not satisfy its regulatory obligations.

II. MOTIONS TO EXCLUDE TESTIMONY

Sandoz moves to exclude the testimony of three experts: Richard Friedlander, M.D., Pamela Kulback, M.D., and Daniel Buffington, Pharm.D.

A. *Daubert* Standard

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony, providing that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. Rule 702 was amended to incorporate the principles first articulated by the United States Supreme Court in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). See FED. R. EVID. 702, Adv. Comm. Notes (2000). Under *Daubert*, expert testimony is admissible only if the proponent demonstrates that: (1) the expert is qualified; (2) the evidence is relevant to the suit; and (3) the evidence is reliable. See *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998); *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 989 (5th Cir. 1997).

Following *Daubert* and its progeny, trial courts act as gatekeepers, overseeing the admission of scientific and nonscientific expert testimony. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999). Trial courts must make “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93. In carrying out this task, district courts have broad latitude in weighing the reliability of expert testimony for admissibility. See *Kumho Tire Co.*, 526 U.S. at 152. The district court’s responsibility “is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.*

Daubert provides the analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. See *Kumho Tire Co.*, 526 U.S. at 141. This *Daubert* framework includes many factors that can be used to determine the admissibility of expert testimony, including, but not limited to, whether the expert’s theory or

technique: (1) can be or has been tested; (2) has been subjected to peer review and publication; (3) has a known or potential rate of error or standards controlling its operation; and (4) is generally accepted in the relevant scientific community. *See Daubert*, 509 U.S. at 593–94. Not every *Daubert* factor will be applicable in every situation and a court has discretion to consider other factors it deems relevant. *See Kumho Tire*, 526 U.S. at 151–52. The Fifth Circuit has directed that, “[i]n the vast majority of cases, the district court first should decide whether the factors mentioned in *Daubert* are appropriate.” *Black v. Food Lion, Inc.*, 171 F.3d 308, 311–12 (5th Cir. 1999). Whether *Daubert*’s suggested indicia of reliability apply to any given testimony is a fact-specific inquiry dependent on the nature of the issue at hand, the witness’s particular expertise, and the subject of the testimony. *Seatrax, Inc. v. Sonbeck Int’l, Inc.*, 200 F.3d 358, 372 (5th Cir. 2000).

Although the *Daubert* analysis is applied to ensure expert witnesses have employed reliable principles and methods in reaching their conclusions, the test does not judge the expert’s conclusions themselves. *Daubert*, 509 U.S. at 594–95. The focus must be solely on principles and methodology rather than the conclusion generated. *Id.* at 995. However, conclusions and methodology are not entirely distinct from one another. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Nothing in *Daubert* or the Federal Rules of Evidence requires a trial court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. *Id.* A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. *Id.*

Notwithstanding the dictates of *Daubert* and its progeny, “the rejection of expert testimony is the exception rather than the rule.” FED. R. EVID. 702, Adv. Comm. Notes (2000). *Daubert* did not work a “seachange over federal evidence law,” and “the trial court’s role as

gatekeeper is not intended to serve as a replacement for the adversary system.” See *id.* (quoting *United States v. 14.38 Acres of Land, More or Less, Situated in Leflore County, Mississippi*, 80 F.3d 1074, 1078 (5th Cir. 1996)). As *Daubert* recognized, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

B. Motion to Exclude the Testimony of Richard Friedlander, M.D.

Sandoz moves to exclude Friedlander’s report because it is factually inaccurate, unreliable, and misleading. Sandoz also moves to exclude Friedlander’s testimony on the grounds that he is not qualified to offer his opinion, his opinions are not based on reliable methodology, his cause-of-death opinion is speculative, his life-expectancy opinion is speculative, and his opinions will not help a jury.

Friedlander is a practicing physician licensed to practice medicine in New York, Florida, and California. Dkt. #88-1 (Friedlander Report) at 2. He is board certified in Internal Medicine (1976) and Cardiovascular Diseases (1979). *Id.* After describing Priest’s relevant medical history, Friedlander offers the following opinions in his report:

- Despite receiving appropriate subsequent care, the pulmonary fibrosis secondary to pulmonary toxicity was irreversible;
- Mr. Priest’s dysphagia, medullary failure, multi-organ failure and resulting cardiac arrest were natural and expected sequelae [consequential conditions] resulting from pulmonary fibrosis secondary to amiodarone toxicity;
- Amiodarone induced pulmonary fibrosis was the primary factor causing Mr. Priest’s death;
- Mr. Priest’s natural life expectancy and resulting positive benefits of his life were cut short.

Id. at 3 (paraphrased). Friedlander states he performed a differential diagnosis or differential etiology and was able to rule out all other causes of death besides amiodarone pulmonary

toxicity. *Id.* at 4. Therefore, he concludes that amiodarone use was in reasonable medical probability a substantial cause of Mr. Priest's death. *Id.*

Sandoz moves to exclude Friedlander's report, pointing out inconsistencies between the report and Friedlander's testimony where Friedlander's testimony corrected inaccuracies in the report. Notably, at his deposition, Friedlander corrected his report opinion that "[Mr. Priest's] dysphagia medullary failure, multiorgan failure and resulting cardiac arrest were natural and expected sequelae resulting from pulmonary fibrosis secondary to amiodarone toxicity" to more accurately state his opinion that Mr. Priest's respiratory insufficiency caused his difficulty swallowing, which caused him to aspirate, which then caused an infection, which led to the multi-organ failure. *Compare* Friedlander Report at 3 *with* Friedlander Depo.⁶ at 271:7-272:7. Sandoz also points out that Friedlander conceded he did not write the report. Dkt. #88 at 6 (citing Friedlander Depo. at 41:18-20 ("Now, specifically, I would point out in this case, the report was offered by the attorney and I merely reviewed it.")). Sandoz does not ask that Friedlander be struck as an expert on this basis, only that his report be deemed inadmissible. Dkt. #88 at 6 ("The numerous inaccuracies and misstatements render the report inherently unreliable and not helpful to the jury. Accordingly, his report should be deemed inadmissible and excluded from the case.")). In response, Plaintiff contends the report is inadmissible hearsay and thus this argument is moot. Dkt. #101 at ¶ 43. As Plaintiff is not trying to admit the report, the court agrees this issue is moot.

Sandoz next argues that because Friedlander is a cardiologist and not a pulmonologist with specific expertise in amiodarone in particular, he is not qualified to give expert testimony in this case. While a pulmonologist or another medical professional with expertise in amiodarone

⁶ Sandoz provides excerpts from Friedlander's deposition at Dkt. #88-2. Plaintiff attaches the full transcript at Dkt. #101-3.

would likely be qualified to testify as an expert in this matter, they are not the only ones. Reviewing his report and deposition, Friedlander's expertise is not so far off the medical issue here that he is not qualified to testify. Sandoz may attack his qualifications through cross-examination, and a jury can decide the appropriate weight to give his opinions.

Sandoz also contends Friedlander's methodology was flawed because he did not review Mr. Priest's "entire medical history" and did not rule out all other possible causes of Mr. Priest's lung disease. Sandoz critiques Friedlander's opinion because he relied on the reports of other medical professionals, such as radiology studies, rather than studying the underlying radiological films themselves. Friedlander is not a radiologist, and the court has little doubt that if he had relied on his own review of the films, Sandoz would have complained he was not qualified to do so. The veracity of the reports that Friedlander relied upon is fodder for cross-examination, not disqualification. Similarly, Sandoz's allegations that Friedlander did not rule out every differential diagnosis is a point for cross examination. As to the one possible alternative cause of Mr. Priest's pulmonary issues that Sandoz points out—interstitial pneumonitis—Friedlander conceded he could not completely rule it out because both interstitial pneumonitis and amiodarone can cause inflammation, but he "didn't see anything clinically that pointed him in that direction [of interstitial pneumonitis]." Friedlander Depo. at 230:7-23.

Sandoz's attacks on Friedlander's opinions regarding Mr. Priest's cause of death—that complications from Mr. Priest's use of amiodarone led to his respiratory insufficiency and weight loss, which led to his difficulty swallowing, which caused him to aspirate, which led to an infection, which caused Mr. Priest's multi-organ failure—similarly attempt to hold Friedlander to an impossible standard of medical certainty beyond what is required by the law. Friedlander

is qualified to give his opinion and his opinions are based on a reliable methodology, even if Sandoz does not agree with the opinions.

Finally, Sandoz attacks Friedlander's opinion that Mr. Priest would have lived several more years had it not been for the complications related to taking amiodarone. Friedlander reviewed Mr. Priest's medical records and is qualified to opine on the expected outcomes of Mr. Priest's health issues.

"[T]he rejection of expert testimony is the exception rather than the rule." FED. R. EVID. 702, Adv. Comm. Notes (2000). Sandoz may disagree with Friedlander's opinions, but he is qualified to give them, they are based on reliable principles and methodologies, his opinions are relevant, and they assist the trier of fact in determining the cause of Mr. Priest's death. Sandoz can attack his opinions through "[v]igorous cross-examination [and] presentation of contrary evidence." *See Daubert*, 509 U.S. at 596. The court will deny this motion.

C. Motion to Exclude the Testimony of Pamela Kulback, M.D.

Sandoz moves to exclude Kulback's opinions on the grounds that she is not qualified to opine on Mr. Priest's prognosis or cause of his medical conditions and her opinions are unreliable and/or irrelevant.⁷

Kulback is a practicing physician licensed in several states. Dkt. #86-2 (Kulback Report) at 2. She is a board certified in Radiology (1988) and completed a fellowship in Cardiothoracic Radiology at the University of Alabama Hospitals, Birmingham (1988-89). *Id.* Kulback's report is short—three single spaced pages—and after describing Mr. Priest's medical history concludes with her opinions:

⁷ Sandoz also argues Kulback should not be allowed to testify about the cause of Priest's death because it was not addressed in her report. Plaintiff agrees that Kulback will not testify about Priest's cause of death. Dkt. #105 at ¶ 16.

In summary, Mr. Priest's clinical history, his radiological findings and pulmonary function tests are compatible with pulmonary fibrosis. Since Mr. Priest's pulmonary symptoms began within a few months of starting Amiodarone treatment, it is my opinion that they are most likely secondary to Amiodarone lung toxicity.

Id. at 3.

Sandoz argues that her opinions should be excluded because she does not diagnose or treat patients with AIPT. Sandoz also argues that her opinions do not "fit" the case because they are unreliable or irrelevant. Kulback gave the opinions that Mr. Priest's radiological findings and pulmonary function tests are compatible with pulmonary fibrosis and given the timing are "most likely" secondary to Amiodarone lung toxicity. *See id.* at (emphasis added). She did not definitively diagnose Mr. Priest with AIPT. Sandoz's critique that Kulback's opinion that the pulmonary symptoms began after starting amiodarone is inaccurate was corrected at her deposition where she stated that the symptoms increased after he began taking amiodarone.

Kulback's opinions are very limited, and she relied on her medical experience and Mr. Priest's pertinent medical records to form her opinions. She is qualified to give the opinions she provided, they are relevant to the case, and they will assist a jury in reaching its decisions. Sandoz's arguments to exclude Kulback's opinions stretch the opinions that Kulback provided in her report and presume that medical professionals cannot have differing medical opinions. Sandoz's attacks on Kulback's opinions are best presented through vigorous cross-examination and the presentation of contrary evidence. *See Daubert*, 509 U.S. at 596. The court will deny this motion.

D. Motion to Exclude the Testimony of Daniel Buffington, Pharm.D.

Daniel Buffington, Pharm.D., offers the opinions that the Medication Guide provided by Sandoz did not comply with the Food and Drug Administration's ("FDA") requirements and

Sandoz failed to ensure that either the amiodarone dispenser or the patient received and FDA-compliant Medication Guide. Dkt. #112-1 (Buffington Report). Specifically, Buffington criticizes Sandoz's method of attaching a strip of Medication Guides to the amiodarone containers and requiring the pharmacist to cut off a Medication Guide from the strip and attach the Medication Guide to the patient's prescription bottle. *Id.* at 4-5. Buffington contends the format of Sandoz's strip Medication Guides is inconsistent with the FDA's sample Medication Guide. *Id.* at 4. Buffington opines that Sandoz's non-compliant methodology forced pharmacies, including the Kroger where Mr. Priest filled his prescription, to come up with their own methods of dispensing the Medication Guides. *Id.* at 4-5.

Sandoz moves to exclude his testimony on the grounds that he is not qualified to opine on regulatory compliance, his opinions on whether Sandoz's Medication Guides comply with federal law are unsupported and unreliable, and his opinions interpreting federal regulations are inadmissible legal conclusions.

Buffington's opinions are best understood in the context of Sandoz's summary judgment motion, and they are discussed in more detail in the undersigned's analysis of that motion. *Infra*. For the reasons given by Sandoz in its motion to exclude and because Buffington's opinions are not relevant to the pleaded claims, as described in the undersigned's summary judgment analysis, *infra*, the undersigned will grant Sandoz's motion and exclude Buffington's opinions as unreliable and irrelevant to the issues in this case.

III. MOTION FOR SUMMARY JUDGMENT

As described above, the court previously allowed Plaintiff to bring claims for gross negligence and negligence per se for Sandoz's alleged failure to provide the required Medication Guides to the pharmacy where Mr. Priest filled his prescription. Under Texas law, "[t]he

elements of a negligence cause of action are the existence of a legal duty, a breach of that duty, and damages proximately caused by the breach.” *IHS Cedars Treatment Ctr. of DeSoto, Tex., Inc. v. Mason*, 143 S.W.3d 794, 798 (Tex. 2004). “[G]ross negligence involves two components: (1) viewed objectively from the actor’s standpoint, the act or omission complained of must involve an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (2) the actor must have actual, subjective awareness of the risk involved, but nevertheless proceed in conscious indifference to the rights, safety, or welfare of others.” *Texas Dep’t of Parks & Wildlife v. Miranda*, 133 S.W.3d 217, 225 (Tex. 2004). “Negligence per se is a tort concept whereby the civil courts adopt a legislatively imposed standard of conduct as defining the conduct of a reasonably prudent person. The unexcused violation of a statute constitutes negligence as a matter of law if such statute was designed to prevent injury to the class of persons to which the injured party belongs.” *Moughon v. Wolf*, 576 S.W.2d 603, 604 (Tex. 1978); *Perry v. S.N.*, 973 S.W.2d 301, 306 (Tex. 1998).

Plaintiff’s gross negligence and negligence per se claims are based on Sandoz’s alleged failure to comply with its obligation to supply amiodarone distributors with the FDA-required Medication Guides, and this failure proximately caused Mr. Priest to take amiodarone without knowledge of the FDA-approved warnings. Sandoz argues it is entitled to summary judgment on the bases that it provided the Medication Guides to the pharmacy, that Plaintiff cannot meet her burden of proof to show Mr. Priest’s death was caused by amiodarone, and Plaintiff does not have clear and convincing proof of gross negligence to support punitive damages.

A. Summary Judgment Standard

Summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure only “if the movant shows there is no genuine dispute as to any material fact and that the movant

is entitled to judgment as a matter of law.” FED. CIV. P. 56(a). A dispute is genuine only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986).

The party moving for summary judgment bears the initial burden of “informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrates the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmoving party to establish the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585–87 (1986); *Wise v. E.I. Dupont de Nemours & Co.*, 58 F.3d 193, 195 (5th Cir. 1995). The parties may satisfy their respective burdens by tendering depositions, affidavits, and other competent evidence. *Estate of Smith v. United States*, 391 F.3d 621, 625 (5th Cir. 2004).

The court will view the summary judgment evidence in the light most favorable to the non-movant. *Griffin v. United Parcel Serv., Inc.*, 661 F.3d 216, 221 (5th Cir. 2011). The non-movant must respond to the motion by setting forth particular facts indicating that there is a genuine issue for trial. *Miss. River Basin Alliance v. Westphal*, 230 F.3d 170, 174 (5th Cir. 2000). “After the non-movant has been given the opportunity to raise a genuine factual issue, if no reasonable juror could find for the non-movant, summary judgment will be granted.” *Id.*

B. Duty to Provide Medication Guides

Sandoz moves for summary judgment on the ground that it provided the Kroger pharmacy where Priest filled his prescriptions with an adequate number of Medication Guides or the means to produce the Medication Guides in sufficient numbers. Federal regulations describe Sandoz’s duty to provide the Medication Guides:

(a) The manufacturer of a drug product for which a Medication Guide is required under this part shall obtain FDA approval of the Medication Guide before the Medication Guide may be distributed.

(b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

21 C.F.R. § 208.24(a)-(b). Sandoz submitted evidence that the FDA approved its Medication Guide. Dkt. #92-9 (Seitz Aff.) at ¶ 34, pg. 54-59, 95-96; Dkt. #92-11; *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (articulating the “duty of sameness”—the requirement that a generic drug’s labeling be the same as the branded drug).

Sandoz also submitted evidence that it provided Medication Guides to Kroger and provided Kroger a means to produce them for each patient receiving amiodarone. Specifically, Sandoz corporate representative, Lisa Tinsley, testified that she reviewed the packaging batch records and bills of materials for amiodarone shipments for two years prior to when Mr. Priest filled his prescription and confirmed that all shipments included four Medication Guides per bottle of amiodarone shipped. Dkt. #92-13 (“Tinsley Depo.”) at 155-159. Ms. Tinsley also testified her investigation found no issues associated with the labeling process for amiodarone during the relevant time period. *Id.* at 92-95. Thus, Sandoz provided evidence that every shipment of its amiodarone from which Mr. Priest’s prescription could have been filled was shipped with adequate numbers of Medication Guides. *See also* Dkt. #92-9 (Seitz Aff.) at ¶ 41. The amiodarone bottles also contained a notice to the pharmacist directing the pharmacist to provide the patient with a Medication Guide, and the Medication Guide included an online

address where it could be found. *Id.* at ¶ 33-34, 43; Dkt. #92-9 at 54-59, 96. The Medication Guides were also available through the DailyMed and FDA websites. Dkt. #92-9 (Seitz Aff.) at ¶ 43. DailyMed is the official provider of FDA label information. *Id.* at n.19.

In support of its motion, Sandoz also submitted two affidavits from Britt Turner, a Kroger Pharmacy Procurement Manager. Dkt. #92-15, 92-16. Turner stated that Kroger distribution centers receive medications from generic pharmaceutical manufacturers. Dkt. #92-16 at ¶ 4. The distribution centers supply individual Kroger pharmacy stores with medications. *Id.* At the distribution center, Kroger employees discard any Medication Guide pads⁸ that are shipped with the medications and do not send those to the pharmacies. *Id.* Kroger pharmacists do not distribute manufacturer-provided Medication Guides. *Id.* at ¶ 7. Instead, Kroger uses an automated system that automatically prints any necessary Medication Guides when a prescription is filled, and that Medication Guide is distributed with the medication. *Id.* at ¶ 5. Kroger's policy is to always distribute required Medication Guides with the medication when it is dispensed. *Id.* at ¶ 6.

A Kroger pharmacist, Kahlil Mohamad, R.Ph., who worked at the Kroger pharmacy where Mr. Priest's prescriptions were filled, testified similarly at his deposition. Dkt. #92-18 ("Mohamad Depo.") 45:21-25.. Mohamad testified that any required Medication Guides automatically print with the prescription receipt, both of which are then packaged with the medicine in a plastic bag until they are picked up by the patient. *Id.* at 23:10 -24:10; 25:10-26:18; 31:9-15. Mohamad testified that many drugs he dispenses require Medication Guides, including "[h]ydrocodone, codeine, nonsteroidal anti-inflammatory like Ibuprofen, Advil, Meloxicam antianxiety, antidepressant drugs, Lexapro, Citalopram and many more." *Id.* at

⁸ As described by a Kroger pharmacist, *infra*, Medication Guides can come in several forms including tear off pads.

31:16-25. He further testified that all of the Medication Guides at his pharmacy are printed from Kroger's software system. *Id.* at 34:20-25. However, he also stated that they do receive some medication guides or other kinds of materials from "[manufacturing] companies." *Id.* at 35:6-13. "I've seen medication guide comes in the box from companies [sic]. They come in stacks for certain medicine. They come sometimes stuck on the bottle, glued to the bottle on top or on the bottle, they stack like this on each bottle so you can take out and use them." *Id.* at 35:19-24. Medication Guides that come from the manufacturer are sometimes just thrown away. *Id.* at 66:15-20. Kroger provides the Medication Guide it prints from its system, which is equivalent to the guide from the manufacturer. *Id.* at 36:5-6; 66:3-14.

Accordingly, Sandoz has shown that it provided the Medication Guides or made them available to the Kroger where Mr. Priest filled his prescription as it was required to do. To counter this evidence, Plaintiff objects to Sandoz's use of the "hearsay Kroger affidavit"; submits the deposition of Mrs. Priest, who generally testified that Mr. Priest did not receive a Medication Guide; and contends the evidence, including the expert report of Dan Buffington, Pharm.D., demonstrates Sandoz failed to comply with the Medication Guide requirements.

1. Britt Turner's Affidavits

In support of its motion, Sandoz also submitted two affidavits from Britt Turner, a Kroger Pharmacy Procurement Manager. Dkt. #92-15, 92-16. Plaintiff objects to the "hearsay Kroger affidavit." While Plaintiff is correct—the affidavit is an out of court statement submitted for the truth of the matter asserted—the same is true for Mrs. Priest's deposition testimony, as well as all depositions and affidavits used at the summary judgment stage. *See* FED. R. EVID. 801 (defining hearsay). However, hearsay is admissible when a federal statute, the Federal Rules of Evidence, or other rules prescribed by the Supreme Court allow its use. FED. R. EVID. 802. A party

moving for or opposing summary judgment can cite to depositions, documents, affidavits or declarations, among other things. FED. R. CIV. P. 56(c)(1)(A), (c)(4). Accordingly, as Plaintiff offers no more specific objection to the affidavit other than the general statement that it is hearsay and no other basis to challenge its reliability, the undersigned overrules the objection.

2. *Mrs. Priest's Testimony*

Plaintiff argues that Mr. Priest did not receive any verbal or written warnings about the dangers of amiodarone. According to Mrs. Priest's deposition, and undisputed by Sandoz, Mr. Priest filled all of his amiodarone prescriptions at Kroger. Dkt. #110-1 (Margaret Priest Depo.) at 94:10-12. She did not recall seeing him receive any printed material about amiodarone. *Id.* at 94:1-4-9, 94:25-95:5, 136:3-18. She testified that Mr. Priest kept copies of papers that came from the pharmacy in a particular box that contained labeled boxes to read and bills. *Id.* at 81:24-82:5. She further testified that no one had discussed the risks of amiodarone with her or her husband, that she and her husband discussed his medications, and if Mr. Priest had been given anything warning him about amiodarone, she would have known about it or found it "in one of his little boxes, but we didn't." *Id.* at 187:20-188:23. She also testified that "he was shocked, you know, when he was told what he got from this stuff, the poison." *Id.* at 188:22-23.

Plaintiff argues Mrs. Priest's testimony that Kroger never provided a Medication Guide to Mr. Priest raises a genuine fact issue. Dkt. #110 at 16. However, Mrs. Priest's testimony only relates to whether Mr. Priest received a Medication Guide from Kroger. Her testimony is not at all probative of whether Sandoz provided the Medication Guides to Kroger. Mrs. Priest's testimony alone⁹ does not raise a material fact issue as to whether Sandoz adequately provided Kroger with Medication Guides.

⁹ The court's conclusion might be different if Mrs. Priest's testimony was paired with testimony from a Kroger employee that they always provided Medication Guides if such Guides were provided and if they did not provide a

3. *Compliance with Medication Guide Requirements*

Plaintiff, in part based on the expert report of Dan Buffington, Pharm.D., argues that Sandoz's procedures did not satisfy its duty to provide the Medication Guide to Kroger. Plaintiff argues that Kroger's use of its own system to print Medication Guides demonstrates Sandoz's failure to adequately provide the Medication Guides. Plaintiff also argues that Sandoz offers no evidence that the FDA has approved Sandoz's process for distributing the Medication Guides¹⁰ and Sandoz has no evidence that it took any measures to validate the efficacy of its distribution methods. However, Plaintiff fails to specifically identify any evidence that contradicts Sandoz's motion. Instead, Plaintiff vaguely argues:

Plaintiff's expert Dr. Dan Buffington has provided reliable opinions on Sandoz failure to comply with its medication guide requirements. *See* Exhibit 5 Dr. Buffington's report includes:

Pharmacies have been unable to rely on Sandoz to ensure provision of sufficient numbers of MedGuides and have had to develop their own methods to comply with the dispensing of "legible and clearly presented" MedGuides to appropriate patients.

Dkt. #110 at 16-17. Plaintiff cites no other evidence in its response to support its position.

Plaintiff's response is entirely insufficient to show Sandoz's procedures did not satisfy its duty to provide the Medication Guides to Kroger. First, Plaintiff seems to expect the court to review Buffington's report and figure out why Sandoz's procedures are allegedly inadequate. Unfortunately, it is Plaintiff's burden to oppose the summary judgment, not the court's. "A party asserting that a fact . . . genuinely disputed must support the assertion by: (A) citing to particular parts of the materials in the record" FED. R. CIV. P. 56(c)(1)(A).

Medication Guide it was only because such a Guide was not provided by the manufacturer. However, that is not the evidence before the court, and the evidence before the court is that Kroger had its own procedures to always provide medication guides where required.

¹⁰ Plaintiff contends the FDA approved the content of the Medication Guides, not their format. Sandoz disputes this, providing evidence the FDA was aware of Sandoz's use of "strip" Medication Guides.

That Kroger implemented its own system to provide the required Medication Guides, without more, is not probative of whether Sandoz adequately provided the Medication Guides to Kroger. Common sense and experience allows any reasonable person to appreciate the burdensomeness of the requirement to sometimes pass out specific pre-printed materials in different forms, from different manufacturers, with particular medications; automation of this process makes sense. *See* Dkt. #92-18 (“Mohamad Depo.”) at 31:16-25 (listing various medications that require medication guides) and 35:19-24 (listing the various forms of medication guides). Thus, by itself, the fact that Kroger developed its own methods to comply with its obligation to provide Medication Guides to patients, *see* 21 C.F.R. § 208.24(e), is not probative of whether Sandoz met its obligations to provide Medication Guides to Kroger. Plaintiff does not point to any evidence that Kroger created its system because Sandoz’s Medication Guides were inadequate, as Plaintiff attempts to imply. Buffington attempts to use the existence of Kroger’s automated system as evidence of Sandoz’s non-compliance. However, he fails to provide any analysis whatsoever on this issue.¹¹ He does not, nor does Plaintiff, cite any Kroger employee affidavit or deposition testimony stating the system was created because Sandoz or any drug manufacturer failed to comply with its obligation to provide Medication Guides. He does not link in time the creation of Kroger’s system with any complaints about Sandoz’s Medication Guides. He does not consider the number of medications requiring Medication Guides, the different forms of Medication Guides, or the burden on the pharmacist in not using an automated system. Buffington’s opinion is entirely without any intellectual rigor or any indicia of reliability. *See Kumho Tire Co.*, 526 U.S. at 152 (the objective of *Daubert*’s gatekeeping requirement is to require an expert’s intellectual rigor); *Seatrax, Inc.*, 200 F.3d at

¹¹ He similarly fails to provide any support for his opinion that the font size, clarity, or strip-format of the Medication Guide fail to comply with relevant federal regulations. However, as discussed below, these opinions are not relevant to any issue actually pleaded and at issue in this case.

372 (same). His opinion rests on his own *ipse dixit*. See *Joiner*, 522 U.S. at 146 (“A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”). His opinion should be excluded as unreliable and, as discussed below, not relevant to any claim in the case.

Moreover, as Sandoz argues in its reply, the theory that Sandoz’s Medication Guides fail to comply with federal regulations is not the claim that Plaintiff pleaded. Nowhere in the FAC did Plaintiff allege Sandoz’s Medication Guide did not comply with federal regulations. As Plaintiff admits, “Daniel Buffington, Pharm.D., is primarily addressing compliance.” Dkt. #100 at ¶ 6. Plaintiff’s FAC alleges Sandoz *failed to provide* Medication Guides, not that its Medication Guides *failed to comply* with federal regulations. See FAC at ¶ 75 (describing failure of manufacturers to provide Medication Guides in sufficient numbers a significant safety issue), ¶ 81 (“The Kroger Pharmacy providing Noel Priest with Amiodarone did not provide him with the Medication Guide. Kroger did not provide it because Sandoz did not provide Medication Guides to Kroger Had he been provided the Medication Guide, he would have been aware of the serious lung related side effects that could lead to death as well as other issues and he would not have taken Amiodarone.”), ¶¶ 84 & 85 (“Because he was not provided a Medication Guide, Noel Priest did not know”), ¶ 122 (“no Medication Guide was provided to Noel Priest by Defendant”), ¶ 125 (“According to the Kroger Pharmacy, Defendant was not providing them or the patients with Medication Guides at the time of the events made the basis of this complaint.”), ¶ 133 (“By failing to provide a Medical Guide”).

A claim which is not raised in the complaint but, rather, is raised only in response to a motion for summary judgment is not properly before the court.” *Cutrer v. Bd. of Supervisors of La. State Univ.*, 429 F.3d 108, 113 (5th Cir. 2005). “Accordingly, a district court considering a

defendant's motion for summary judgment does not err by disregarding a theory of liability asserted in the plaintiff's response that was not pleaded as required by the applicable pleading standard." *Hoffman v. L&M Arts*, 838 F.3d 568, 576 (5th Cir. 2016) (internal citations omitted). Accordingly, as Plaintiff never pleaded that Sandoz's strip Medication Guide failed to comply with the necessary regulations, this is not a proper ground on which to oppose summary judgment.

Further, this new theory of the case raises preemption issues that were not previously before the court. The undersigned recommended allowing the failure to provide Medication Guide claims to go forward as not preempted because Plaintiff represented that "[a]ccording to the Kroger Pharmacy, Defendant was not providing them or the patients with Medication Guides." Dkt. #65 (First R&R) at 12 (quoting FAC at ¶¶ 81, 125); *see also* FAC at ¶¶ 75, 84, 85, 122, 133. The undersigned recommended that Plaintiff's claim be allowed to go forward "[t]o the extent Plaintiff seeks to allege that Sandoz failed to comply with its obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused Mr. Priest to take amiodarone without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt's* reasoning." Dkt. #65 (First R&R) at 12. As pleaded in the FAC, the basis for Plaintiff's claim that Sandoz failed to supply distributors with FDA-required Medication Guides was not that the Medication Guides did not comply with FDA requirements but that, as required by the FDA, they were not provided to distributors or dispensers. The court did not examine whether a claim that Medication Guides themselves did not comply with federal regulations would be preempted. However, as this new theory is not properly before the court, the court does not need to reach the issue of whether this theory presents preemption problems.

4. *Conclusion*

Federal regulations require that drug manufacturers, when required, ensure Medication Guides are available to be distributed to patients by either providing Medication Guides in sufficient numbers to distributors or dispensers or by providing them the means to produce Medication Guides in sufficient numbers. 21 C.F.R. § 208.24(b). The uncontroverted evidence shows that Sandoz provided amiodarone with Medication Guides to the Kroger distribution center. The Kroger distribution center ships the medications to the Kroger pharmacies, where the medications are dispensed to patients. Kroger, however, uses its own automated system to print the various Medication Guides for the drugs it dispenses, and the manufacturer's Medication Guides are discarded at the distribution center or the pharmacy.

Plaintiff, with no legal support, citation, or even argument, attempts to recast Sandoz's duty as ensuring the Medication Guide is actually given to the patient. However, that is not the duty, nor is that the claim that the court allowed to go forward. *Compare* 21 C.F.R. § 208.24(b) (manufacturer's duty to provide Medication Guides to distributors, packers, or dispensers) *with* § 208.24(c) (distributor's or packer's duty is to provide Medication Guides to the dispensers) *and* § 208.24(e) (dispenser's duty is to provide the Medication Guide to the patient); Dkt. #65 (First R&R) at 12, 16-17.

By itself, Mrs. Priest's deposition testimony that Mr. Priest did not receive a Medication Guide from the Kroger pharmacy when he filled his prescriptions, even when fully believed, is not probative of whether Sandoz adequately shipped Medication Guides or made them available to the Kroger distribution center. There are simply too many intervening steps, and in this case too much uncontroverted evidence, between the amiodarone arriving at the Kroger distribution center and being dispensed to Mr. Priest for her testimony to raise a genuine issue of material

fact as to whether Sandoz adequately shipped Medication Guides with the amiodarone.

Plaintiff's reliance on Buffington's opinion also fails to raise a material fact issue. His opinions are unreliable and not relevant to any pleaded issue in this case.

Accordingly, Sandoz has shown that it satisfied its duty to provide Medication Guides, and Plaintiff has failed to raise a question of material fact on this issue. Sandoz is entitled to summary judgment on this issue.

C. Medical Causation

Sandoz contends Plaintiff cannot show amiodarone caused Mr. Priest's death. Sandoz's argument is entirely based on its *Daubert* motions to exclude Plaintiff's experts Drs. Friedlander and Kulback. As the court is denying those motions, *supra*, Sandoz has not showed it is entitled to summary judgment on the issue of medical causation.¹²

D. Clear and Convincing Evidence

Sandoz argues Plaintiff has not satisfied her heightened burden to show gross negligence to support punitive damages. As Plaintiff has not raised a material fact issue that Sandoz breached its duty or was grossly negligent, the court agrees Plaintiff also cannot meet its burden under a heightened proof standard.

E. Conclusion

Although Sandoz has not shown it is entitled to summary judgment on the issue of medical causation, for the reasons discussed above, Sandoz has shown it is entitled to summary judgment on the issues of whether it breached its duty to provide Medication Guides and whether Plaintiff can show a breach of that duty by clear and convincing evidence. Accordingly, the undersigned will recommend that Sandoz's motion for summary judgment be granted.

¹² Although Plaintiff has raised a fact issue on medical causation, the undersigned questions whether Plaintiff would be able to prove proximate cause in light of the uncontradicted evidence that no matter the number or form of Medication Guides provided by manufacturers, Kroger discarded those Guides in favor of its own system.

IV. ORDERS

As stated, the court **ORDERS** that Sandoz's Motion to Exclude Testimony of Pamela Kulback, M.D. In Part (Dkt. #86) is **DENIED**; Sandoz's Motion to Exclude the Testimony of Richard Friedlander, M.D., In Part (Dkt. #88) is **DENIED**; and Sandoz's Motion to Exclude the Testimony of Daniel Buffington, Pharm.D., In Part (Dkt. #88) is **GRANTED**.

V. RECOMMENDATIONS

In accordance with the foregoing, the undersigned **RECOMMENDS** that Sandoz's Motion for Summary Judgment (Dkt. #92) be **GRANTED** and Plaintiff's claims be **DISMISSED WITH PREJUDICE**.

VI. OBJECTIONS

The parties may file objections to this Report and Recommendation. A party filing objections must specifically identify those findings or recommendations to which objections are being made. The District Court need not consider frivolous, conclusive, or general objections. *See Battles v. United States Parole Comm'n*, 834 F.2d 419, 421 (5th Cir. 1987).

A party's failure to file written objections to the proposed findings and recommendations contained in this Report within fourteen (14) days after the party is served with a copy of the Report shall bar that party from de novo review by the District Court of the proposed findings and recommendations in the Report and, except upon grounds of plain error, shall bar the party from appellate review of unobjected-to proposed factual findings and legal conclusions accepted by the District Court. *See* 28 U.S.C. § 636(b)(1)(C); *Thomas v. Arn*, 474 U.S. 140, 150-53 (1985); *Douglass v. United Services Automobile Ass'n*, 79 F.3d 1415 (5th Cir. 1996)(en banc).

SIGNED December 28, 2017



MARK LANE
UNITED STATES MAGISTRATE JUDGE